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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,308	06/27/2001	Keith A. Crutcher	874000001COE	2346
27572	7590	06/30/2005	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/892,308

Applicant(s)

CRUTCHER ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 17 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2, 17 and 35-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed March 01, 2004. Upon entering the amendment, the claims 35 and 37-38 are amended.

The claims 2, 17 and 35-39 are now pending and presented for the examination. The following rejections are made.

Response to Arguments

2. Applicant's arguments filed 3/1/04 have been fully considered but they are not persuasive.

102 Rejection

In response to Applicant's argument that Ban et al(US'347) does not anticipate the claims because US'347 teaches heparan sulfate like substances by allegedly stating that Ban et al. nowhere teach or suggest that the "heparan sulfate like substances" is heparan sulfate.

However, applicant's argument is not persuasive because heparan like substances, in fact, include heparan itself because heparin is only compound that is perfectly heparan like. Even if, the said heparan sulfate like substances (US'347) does not include heparan sulfate itself, it would have been readily apparent to any ordinary skilled artisan that the heparan sulfate like substances and heparan sulfate should be functionally equivalent to each other where there are no other explanations to describe the said substances. The said substances must share a common characteristic that represents

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heparan. Therefore, one would have envisaged same results from employment of heparan sulfate or heparan sulfate like substances.

In response to applicant's argument that ateroid contains a number of compounds other than sulfomucopolysaccharides and sulfomucopolysaccharides also contains a number of compounds other than heparan sulfate like substances.

However, the claims are met because as clearly stated in US'347, at column 4, lines 30-33, the sulfomucopolysaccharides mixture comprising heparan sulfate like substances improves Alzheimer type senile dementia remarkably. Therefore, the claimed subject matter(i.e. a method of treating a mammal having condition(Alzheimer type senile dementia) comprising administering a compound such as heparan sulfate) are clearly embraced and anticipated .

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

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Thus, 102 rejection previously issued should be maintained as same and all the claims including currently amended 35, 37-38.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2, 17, 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ban et al(US 4,956,347).

The instant claims are directed to a method of treating a condition(e.g. Alzheimer type senile dementia or arteriosclerosis) associated with toxicity caused by a peptide fragment of apolipoprotein E(MW \geq at least 5kD) using an effective amount of heparan sulfate to affected cells of the said condition via preventing toxicity to said cells.

Ban et al teach a treatment of Alzheimer-type senile dementia using a therapeutically effective amount of heparan sulfate like substance, see column 4m lines 25-50. It further states that sulfonucopolysaccharide(e.g. heparan sulfate like

substance) is conventional therapeutic modality for atherosclerosis, see column 3, lines 1-10. One would have envisaged that heparan sulfate like substance would have included heparan sulfate and any substance having heparan sulfate moiety. Thus, all the critical elements required by the claims are well taught cited reference.

As to claims 2, 17, 35-37, Ban et al's teaching inherently possesses the feature(i.e. preventing toxicity caused by a peptide fragment(141-147) of apolipoprotein E(MW \geq at least 5kD)) recited in the said claims. Since the said feature is considered to be an underlying mechanism for said treatment wherein it is naturally achieved when heparan sulfate is administered to the affected cell to treat Alzheimer-type senile dementia or atherosclerosis. The said feature does not have patentably weight in this case and is not considered to be a patentably distinct subject matter over the teaching of the prior art of the record.

Thus, all the claimed subject matter is anticipated by the cited reference and the claims are properly included in this rejection.

Conclusion

3. No claim is allowed.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

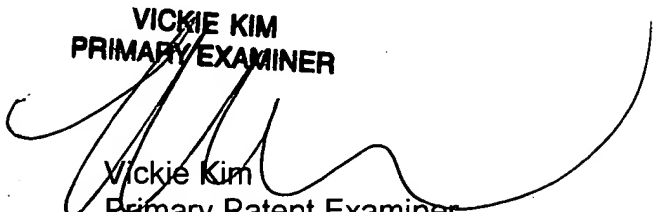
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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VICKIE KIM
PRIMARY EXAMINER



Vickie Kim
Primary Patent Examiner
June 27, 2005
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